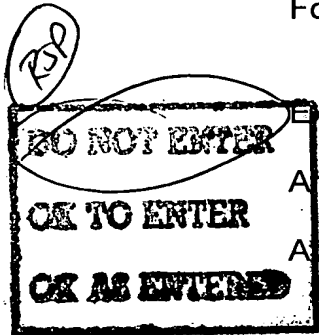


ARK:jsg072701/6711002CIP-3.RESFOA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant : William J. Schmidt  
Serial No. : 09/385,405  
Filed : August 30, 1999  
For : METHOD FOR THE PURIFICATION AND  
RECOVERY OF WASTE GELATIN  
Examiner : R. Popovics  
Art Unit : 1723  
Attorney Docket No. : 671.1.002 CIP-3



I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS  
FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON D.C.  
20231  
ON July 30, 2001  
NAME Jill S. Garretson  
SIGNATURE *Jill S. Garretson*

Honorable Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

July 30, 2001

RESPONSE TO FINAL OFFICE ACTION

Dear Sir:

This is a response to the final Office Action of January 30, 2001. Applicant has  
filed concurrently herewith a Petition for a three month extension of time along with the  
requisite fee extending the date for response to July 31, 2001. Applicant has also filed  
concurrently herewith a Notice of Appeal with the requisite fee.

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At the outset, Applicant would like to confirm that the claims of the pending application are those that were finally rejected in the final Office Action of January 31, 2001. Since the issuance of the final Office Action, Applicant, the undersigned and the Patent Examiner held an interview on February 26, 2001 in which, at the request of the Patent Examiner, Applicant filed on March 28, 2001 an Amendment to the final Office Action. This Amendment was submitted after a lengthy interview and after a full review of the proposed claims by the Patent Examiner. Thereafter, the Examiner held a telephonic interview on May 10, 2001 with the undersigned to indicate that the proposed amended claims did not distinguish over the prior art and, if entered, would result in a rejection under 35 U.S.C. Section 102. Accordingly, this response is based on the claims pending in the final Office Action as recited above which Applicant believes are patentable over the references of record in this case.

In conjunction with the following remarks, Applicant submits the executed Declaration of the inventor, William J. Schmidt attesting to his personal knowledge of the state of the capsule manufacturing industry leading up to the present invention and to actual experiments including scale up experiments that were performed during the course of the past three years at commercial facilities to improve upon the technology fairly described in Schmidt U.S. Patent No. 5,288,408 (hereinafter "the '408 Patent").

Claim 1 of the present application is directed to a method of treating a waste material containing gelatin which includes the steps of combining the waste material and a solvent for the gelatin to form a first liquid which contains gelatin, and separating

the first liquid into a solvent based layer and a non-solvent based layer. Of critical importance to the claimed invention is the treatment of the solvent based layer with a process which is selected from a particular group of such processes which are not disclosed in the '408 Patent. These processes are specifically liquid:liquid centrifugation, submicro/micro filtration, liquid:liquid coalescers, and absorbents and combinations thereof.

In the Office Action of January 31, 2001, the Examiner clearly states that "claim 1 appears to differ from Schmidt (the '408 Patent) by specifying a step of "treating the solvent based layer with a filtering process selected from a group consisting of liquid:liquid centrifugation, submicro/microfiltration, liquid:liquid coalescers, and absorbents and combinations thereof".

In the Examiner Interview Summary record of May 22, 2001 there is a detailed analysis of the '408 Patent. As in claim 1 of the presently claimed invention, there is the disclosure of the steps of combining the waste material with a solvent and then separating the solvent based layer from the non-solvent based layer. The '408 Patent teaches filtering the solvent based layer (e.g. the aqueous layer) at an elevated temperature but not in the way claimed in the present application. The Office Action refers to column 3 of the '408 Patent as stating that the soft capsule-forming material may contain a variety of ingredients which may include coloring agents and preservatives. Applicant does not disagree with this statement. However, it should be noted that at column 4, line 10 of the '408 Patent states that the upper phase (the non-solvent phase) may contain lubricating or coating oils, active ingredients, coloring

agents and preservatives which may themselves be subjected to certain novel recycling techniques. Nothing further is said about the upper phase and how one might remove the various components from the same. Thus, according to the '408 Patent, it is within the fair teachings of the reference that certain contaminants will appear in the upper  
5 phase which is not the subject of the claims herein. The present invention is principally concerned with Step (c) of the process recited in claim 1; namely, the treatment of the lower or solvent based phase (e.g. aqueous phase).

Column 4, beginning at line 22 of the '408 Patent refers to the lower phase as being hot filtered at an elevated temperature to remove any remaining traces of oil or  
10 other contaminants. Whatever traces of oil or other contaminants may be present in the lower phase, the '408 Patent is clear regarding how to treat this portion of the waste stream. This is done by stainless steel filtration equipment such as a plate filter, or a coated plate filter like, for example, a Sparkler filter. Alternatively, Nutche filters of the Rosenmund type or cartridge filters may be used for this purpose. One of ordinary skill  
15 in the art would then be led by the '408 Patent to use these filters to treat the lower or aqueous phase. This is the fair teaching of '408 Patent.

Attention is directed to the Declaration of William J. Schmidt who chronicles the efforts made to treat waste stream containing oils with hydrophilic groups, aromatic oils and suspended particles (e.g. titanium dioxide). The Declaration is being submitted in  
20 unsigned form. The executed Declaration will be submitted as soon as it is received. In this regard, various tests were performed by reputable filter companies and capsule manufacturers in an effort to commercialize the '408 Patent technology. The Schmidt

Declaration focuses on test procedures performed on waste gelatin streams that could not be effectively treated by the '408 Patented technology. In this regard, Paragraph 7 of the Schmidt Declaration indicates that the '408 claimed process does not perform on a commercially acceptable scale when the waste gelatin stream contains one or more specific contaminants including oils with hydrophilic functioning groups, such as vitamin E acetate, aromatic oils such as fish oil and garlic oil, and suspended particles such as titanium dioxides.

Since commercial success of the present technology would require the removal of such materials, efforts were made to improve upon the technology of the '408 Patent developing specific treatments that could effectively remove contaminants of interest herein.

In or about August, 1998, tests were performed at General Nutrition Products in which a waste gelatin stream containing gelatin, glycerin and vitamin E acetate (an oil with a hydrophilic functional group) was tested in accordance with the procedure set forth in Paragraph 10 of the Schmidt Declaration. The waste stream was first treated in accordance with the Schmidt '408 Patent using a 10 micron polypropylene cartridge filter. The resulting filtrate was observed to have a milky white and therefore unacceptable appearance due to the presence of residual emulsified oil (oil with hydrophilic functional groups) and was therefore unsuitable for commercial scale recycling of gelatin.

In May, 2000 at another facility, a very similar waste stream as described above was treated with the same cartridge filter taught by the '408 Patent but then was treated in accordance with the present invention using a 0.65 micron tangential flow microfilter (microfiltration). The gelatin recovered from this example was observed to have a clear, 5  
amber appearance typically associated with previous unprocessed gelatin. It was the treatment specifically claimed in the present application which achieved the clear recycled gelatin where the '408 Patented technology did not succeed. Nothing in the '408 Patent teaches or suggests this surprising and unobvious result.

When the resulting recyclable gelatin product was obtained, it was tested for 10  
stability and other characteristics which are a necessary part of using a recycled product as indicated in Paragraph 14 of the Schmidt Declaration. The results showed that the recyclable gelatin obtained in accordance with the present invention was every bit as good as virgin gelatin.

As indicated in Paragraph 16 of the Schmidt Declaration, an effort was made to 15  
modify the process of the '408 Patent to remove residual emulsified oils by using a smaller pore cartridge filter. A 1 micron and 0.3 micron cartridge filter were tested. However, the 1 micron filter was too large to remove the residual oils while the 0.3 micron cartridge filter resulted in an unacceptable throughput.

In a still further effort to modify the '408 Patent, a 0.5 micron cartridge filter was 20  
used at a reduced back pressure. As indicated in Paragraph 18 of the Schmidt Declaration, tests were performed on a waste stream containing gelatin, glycerin and

fish oil. One sample run employed a 1 micron cartridge filter according to the teaching of the '408 Patent. The resulting permeate had a distinct "fishy smell" and therefore did not remove a sufficient quantity of the fish oil. When the process was carried out in accordance with the present invention using a one micron cartridge filter followed by a 0.65 micron tangential flow microfilter (i.e. microfiltration) the resulting permeate was odor free indicating that essentially all of the fish oil had been removed, a surprising and unobvious result of the present application. Indeed, these test results clearly show that modifying the pore size of the '408 Patent technology was not successful in removing the above-mentioned contaminants.

As indicated in Paragraph 19 of the Declaration, similar results have been obtained when the waste stream contains submicron particle size titanium dioxide which is typically suspended in the waste gelatin. It should be noted that the preferred procedure for removing such particles is centrifugation as specifically claimed in the present application.

As previously indicated, the '408 Patent teaches filtering processes at elevated temperatures using cartridge filters and equivalent devices. There is no indication in the '408 Patent of the nature of the particular contaminants, if any, contained in the lower phase and the effectiveness of removing the same through the use of the various specific filters set forth in column 4. As previously indicated, the '408 Patent describes waste gelatin streams in which the vast majority of contaminants may have already been removed in the non-solvent phase leaving very little to remove in the lower phase of the process. The present invention provides that if certain contaminants are present

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(e.g. oils having hydrophilic groups, aromatic oils, and suspended particles) then the technology of the present application must be employed to get an effective recyclable stream on a commercial basis. The Declaration of William J. Schmidt clearly shows that this is the case. Accordingly, the present invention is patentable over what is fairly disclosed in the '408 Patent.

The Schmidt Declaration also shows that leading manufacturers of soft gelatin capsules were introduced to and aware of the '408 Patent technology but did not recognize how to remove the oily contaminants and suspended particles from the waste stream. Had they recognized how to accomplish this task in light of the '408 Patent, they would have done so and would not be engaged in license negotiations for the present technology.

In view of the foregoing, Application submits that the present claims are in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

Applicant is mindful that the rejection in the final Office Action is also based on Fane et al. or Dutre et al. or Chakravorty et al. Insofar as those references are concerned, and as previously explained to the Patent Examiner during the interview and prior thereto, all three references actually teach clear differences in functionality between ultra-filtration and microfiltration. By way of example, Fane et al. states that ultra-filtration is a pressure-driven separation technique based on a semi-permeable membrane which allows the passage of water and ionic species but which restricts the



passage of macromolecules and suspended solids. Thus, in actuality, Fane et al. actually teach that a waste stream of gelatin if treated with ultra-filtration will remove both gelatin and suspended particles from the waste stream while allowing water and ionic species to pass therethrough. Thus, gelatin is not separated from particulates as  
5 is required in the present claims.

Chakravorty et al. and Dutre et al. are fully consistent with the explanation provided by Fane et al. There is no teaching or suggestion in these references that ultra-filtration can be used to separate gelatin from particulates or residual oils as required in the present claims.

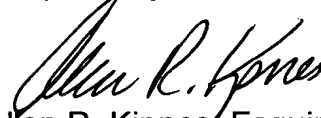
10 In the latest Office Action, reference is made to Figure 3 of the Handbook Of Separation Techniques for chemical engineers as set forth in Paragraph 3 on page 3 of the Office Action. This reference was cited to show an overlap between microfiltration (capable of separating gelatin from particulates and residual oils) and ultra-filtration. However, the bottom of pages 2-5 state that the charts shown in Figure  
15 3 was originally published in 1969 and reflected the confusion in the literature at that time regarding micro-filtration, ultra-filtration and reverse osmosis. However, as shown in Figure 1 on pages 2-5 of the same publication, there was well recognized in 1979 (the date of publication of the handbook) useful definitions of micro-filtration and ultra-filtration showing a clear line of demarcation between the respective systems insofar  
20 as their ability to remove components from a gelatin stream. Thus, the secondary references cited in the final Office Action do not cure the deficiencies of the primary reference.

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In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

It is believed that no fee is due. However, if any fee is due, it should be charged  
5 to Deposit Account No. 23-0510.

Respectfully submitted,



Allen R. Kipnes, Esquire  
Registration No. 28,433  
Attorney for Applicant

Address All Correspondence to:  
Allen R. Kipnes, Esquire  
WATOV & KIPNES, P.C.  
10 P.O. Box 247  
Princeton Junction, NJ 08550  
(609)243-0330